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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,374	04/19/2004	Takayuki Hamada	251990US0	9731
22850	7590	01/17/2006	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			ZUCKER, PAUL A	
			ART UNIT	PAPER NUMBER
			1621	

DATE MAILED: 01/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/826,374

Applicant(s)

HAMADA ET AL.

Examiner

Paul A. Zucker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/10/2004</u> . | 6) <input type="checkbox"/> Other: ____.  |

**DETAILED ACTION**

***Specification***

1. The abstract of the disclosure is objected to because the phrase enclosed in square brackets in the first line should be removed. Correction is required. See MPEP § 608.01(b).
2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-3 are drawn to a production method but do not set forth what the method is intended to produce. It is therefore impossible to determine the intended scope of Applicants' process. Claims 1-3 are therefore rendered indefinite.
4. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the limitation "\*\* indicates an

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optically active carbon atom" in lines 10-11. Optical activity is a property of the molecule as a whole and not the chiral carbon denoted "\*".

5. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 recites the limitation " at a temperature of 5°C **and less**". This recitation makes it unclear whether a temperature of 5°C at some point in the process is required. Claim 7 is therefore rendered indefinite. NOTE: If Applicants do not wish to require a temperature of 5°C the limitation " at a temperature of 5 °C **and less**" should be changed to "at a temperature of 5 °C **or less**".

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Seebach et al (Tetrahedron Letters, 1987, 28(27), pages 3103-3106). Seebach discloses (Page 3105, Scheme 3, top row, second compound from left) the reaction between (R)-methyl 3-trifluoromethanesulfonyloxybutyrate and benzyl amine to give (S)-methyl 3-benzylaminobutyrate. Seebach therefore anticipates claims 1, 4 and 5.

### ***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1, 2 and 4-7 rejected under 35 U.S.C. 103(a) as being unpatentable over Seebach et al (Tetrahedron Letters, 1987, 28(27), pages 3103-3106) when considered with Effenberger et al (Liebigs Annalen der Chemie 1986, page 314-333).

Instantly claimed are methods for the synthesis of optically active  $\beta$  amino acids which comprise reacting an aromatic amine with an optically active sulfonate. The claimed process includes the methods of producing the optically active sulfonate.

Seebach teaches (Page 3105, Scheme 3, top row, second compound from left) the reaction between (R)-methyl 3-trifluoromethanesulfonyloxybutyrate and benzyl amine to give (S)-methyl 3-benzylaminobutyrate.

Seebach does not appear to contemplate the instantly claimed conditions and reactions needed to produce the optically active sulfonate starting material for this reaction.

Effenberger, however, teaches (Page 317, line 7, page 318, Table 1) processes for the synthesis of optically active  $\alpha$  amino acids that differ from the instantly produced products only in the position of the amino group. Effenberger's process is otherwise identical to that instantly claimed other than in the position of the uninvolved carboxyl group. Effenberger teaches (Page 316, first line, transformation  $1 \Rightarrow 3$ ) the synthesis of the desired trifluoromethansulfonyloxy compounds by the use of trifluoromethansulfonic anhydride. Effenberger teaches (Page 324, 3<sup>rd</sup> full paragraph) formation of the trifluoromethansulfonyloxy at  $-30^{\circ}\text{C}$  to  $-35^{\circ}\text{C}$ . Effenberger further teaches (Page 326, Table 5, entry 4g, for example) reaction of the trifluoromethansulfonyloxy compound with an amine at  $0^{\circ}\text{C}$ .

Thus one of ordinary skill in the art would have been motivated by Seebach to seek out and apply Effenberger's conditions for producing the starting materials which Seebach's process requires. There would have been a reasonable expectation for success since the differences between the compounds of Seebach and Effenberger do not materially affect the chemistry involved.

Thus the instantly claimed process would have been obvious to one of ordinary skill in the art.

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8. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Seebach et al (Tetrahedron Letters, 1987, 28(27), pages 3103-3106) and Effenberger et al (Liebigs Annalen der Chemie 1986, page 314-333) as applied to claims 1, 2 and 4-7 above, and further in view of Lemieux et al (Canadian Journal of Chemistry, Biochemistry of the Ustilaginales. IV. The Configuration of Some  $\beta$ -Hydroxyacids and the Bio-reduction of  $\beta$ -Ketoacids 1951, 37(11), pages 678-690).

Instantly claimed are methods for the synthesis of optically active  $\beta$  amino acids which comprise reacting an aromatic amine with an optically active sulfonate. The claimed process includes the method of producing the optically active hydroxyl starting material by asymmetric reduction.

The difference between the process taught by Seebach and Effenberger and that instantly claimed is that neither Seebach nor Effenberger disclose or fairly suggest producing the optically active hydroxyl starting material by asymmetric reduction.

Lemieux, however teaches (Page 686, 1<sup>st</sup> and 2<sup>nd</sup> full paragraphs) the asymmetric synthesis of  $\beta$ -hydroxyacids via the bio-reduction of the corresponding  $\beta$ -ketoacids using Baker's Yeast.

Thus one of ordinary skill in the art would have been motivated to employ the process of Lemieux in order to obtain the  $\beta$ -hydroxyacids required for the methods of Seebach and Effenberger in a cheap cost-effective manner from readily available achiral starting materials.

Thus the instantly claimed process would have been obvious to one of ordinary skill in the art.

### ***Claim Objections***

9. Claims 6 and 7 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim since each of the indicated claims is a multiple dependent claim which is dependent upon another multiple dependent claim or dependent upon one that is. See MPEP § 608.01(n).

### ***Conclusion***

10. Claims 1-7 are pending. Claims 1-7 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 571-272-0650. The examiner can normally be reached on Monday-Friday 5:30-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status



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information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



PAULA A. ZUCKER, PH.D.  
PRIMARY EXAMINER

*Techn Center 1600*